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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 0304

Application Number: 09/757,610
Filing Date: January 11, 2001
Appellant(s): STAMLER ET AL.

Eric S. Spector
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/12/03

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 8-14 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Dermer, Biotechnology 12, 320 (3/94)

Gura, Science 278, 1041-1042 (11/97)

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 8-14 were rejected under 35 U.S.C. 112, first paragraph. This rejection is set forth in prior Office Action, Paper No. 13.

The rejection of claims 8-14 were rejected under 35 U.S.C. 112, first paragraph, made in Paper No: 9 (mailed 10/21/02) was reinstated for the reasons of record and for the additional reasons set forth *infra*. Applicant's arguments were addressed as they pertained to the current grounds of rejection. The specification, while being enabling for administering an inhibitor of glutathione-dependent formaldehyde dehydrogenase does not reasonably provide enablement for killing or reducing the growth of pathologically proliferating mammalian cells *in vivo*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification fails to provide information that would allow the skilled artisan to practice the invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CFAC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Foreman*, 230 USPQ 546 (Bld Apls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction and guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art,

8) the breadth of the claims.

The quantity of experimentation necessary would be undue. The working examples lack sufficient data. Therapies involving cancer and pathologically proliferating cells are unpredictable (see Dermer, Biotechnology, March 12, 1994, vol. 12, pp.320). In Dermer, column 1, 3rd paragraph "petri dish cancer is really a poor representation of malignancy, with characteristics profoundly different from the human disease." The amount of direction and guidance provided is lacking. The working examples lack sufficient data to understand if the clinical results will invariably occur. The specification does not teach how to assess and/or modify each of the variables necessary for the therapy to work.

The working examples provided lack sufficient data to determine how to avoid the pitfalls in the process of using the therapy.

The nature of the invention is concerned with providing therapy for pathologically proliferating mammalian cells. The specification does not enable one skilled in the art to which it pertains, or with which it is most nearly connected, to provide effective therapy for pathologically proliferating mammalian cells.

The state of the prior art is unpredictable when involved with therapies for cancer and pathologically proliferating mammalian cells. (Dermer, Biotechnology, March 12, 1994, vol. 12, pp.320).

The relative skill of those in the art would be a practicing MD skilled in clinical research.

The predictability of the art is that cancer therapies and therapies for pathologically proliferating mammalian cells are unpredictable.

The breadth of the claims- the rejected claims are directed to therapies for cancer and pathologically proliferating mammalian cells but the specification does not so demonstrate.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

Applicant's arguments filed 11/23/02 are not persuasive for the following reasons. Based on the teachings of unpredictability regarding *in vivo* therapy which are taught in the prior art, persons skilled in the art would not associate *in vitro* results with *in vivo* therapeutic efficacy. Applicant's specification fails to contain sufficient disclosure to overcome the teachings of unpredictability which are found in the art. *Ex parte Balzarini* 21 USPQ2d 1892 (BdPatAppl &Int. 1991).

(11) Response to Argument

Appellant argues that the main contention involves the quality of experimentation necessary. Appellant points to prophetic working examples XV-XXVI, page 40-42 of the instant application. The examiner refers to the working examples which contain no control population,

against which to measure the effectiveness of the treatment. The examples contain a single patient data point per example, it is unlikely that useful clinical data would be extrapolated from a single data point. Numerous working examples include regiments or combinations of therapies, which do not speak to the effectiveness of the claimed treatment, D-glutathione, by itself. It is not clear if the effect is due to D-glutathione alone, see working examples XV, XIX, XXI, XXII, XXIII, and XXIV. Finally, no working examples were provided to show the claimed effectiveness against pathologically proliferating cells comprising pathologic bacteria or fungus which kill the pathologic bacteria or fungus or reduce the rate of proliferation of the pathologic bacteria or fungus by at least 10% (claim 9 of the instant claims).

Appellant contends there is an error firstly in the rejection of claims 8-14 in that it fails to recognize that the only question involved in determining enablement in this case is whether the specification teaches how to use. The examiner contends that this was not an enablement rejection, but a scope of enablement rejection. The specification, while being enabling for administering an inhibitor of glutathione-dependent formaldehyde dehydrogenase does not reasonably provide enablement for killing or reducing the growth of pathologically proliferating mammalian cells *in vivo* using the inhibitor, D-glutathione.

Appellant contends that even if the WANDS factor are pertinent, there is error secondly, in respect to the rejection of claims 8-14 because the office action fails to consider pertinent prior art, namely Stamler, USPN 6,057,367. The examiner contends that the '367 patent is directed to treating mammals for infections and with conditions associated with pathologically proliferating cell growth by administration of a manipulator of nitrosative stress to selectively kill or reduce the growth of microbes or helminthes causing the infection or of host cells infected with the

microbes or of the pathologically proliferating mammalian cells. The examiner points out that the '367 patent does not use the claimed invention of the instant application, the inhibitor, D-glutathione.

Appellant contends there is error thirdly, in respect to the rejection of claims 8-14 because of the position in the rejection that the examples lack sufficient data to understand if clinical results will invariably occur. Appellant points to treatment received by his wife for severe rheumatoid arthritis which did not work, was of great expense, and yet has FDA approval. The examiner sadly contends that this is evidence of the unpredictability in the art.

Appellant contends there is error fourthly because the rejection takes the position that there is no enablement because the working examples provided lack sufficient data to determine how to avoid the pitfalls in the process of using the therapy. The examiner contends that this rejection, in paper No:9, using the Gura reference, was withdrawn and replaced with the current rejections of paper No:13, using the Dermer reference.

Appellant contends there is an error fifthly because the final office action gives up on Dermer to prove unpredictability. Appellant contends that the office action does not say what the prior art is. The examiner contends that the prior art is the Demer reference of unpredictability in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Roy Teller
March 3, 2004
RT

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